MAY - 4 2011

Genoss Co., Ltd.
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GENOSS

510(k) Summary

1. Company

	Submitter
Name	GENOSS Co., Ltd.
Address	1F Gyeonggi R&DB center, 906-5 Iui-dong, Suwon-si, Yeongtong-gu, Gyeonggi-do, 433-270, Korea
Phone/Fax	+82-31-888-5100/ +82-31-888-5105
Contact Person	Hoseog Cha / QA Team leader hscha@genoss.com
Summary Date	March 8, 2011

2. Device Name

Proprietary name: GENOSS Collagen Membrane
Common name: Resorbable dental barrier membrane, animal source
Classification name: Barrier, animal source, dental

3. Predicated Device

RCM6 membrane (K003339)
Fortgen Oral Membrane (K071555)
OSSIX Plus (K053260)

4. Description

GENOSS Collagen Membrane is a resorbable membrane to aid the regenerative healing of bone or bone/periodontal ligament defects of the oral cavity.
GENOSS Collagen Membrane is designed to be a passive barrier which excludes epithelial and gingival connective tissue from the defect site so that only the desirable cells repopulate the space, allowing regeneration to occur. Its resorbability eliminates the need for a second surgery.

GENOSS Collagen Membrane is made from bovine tendon, the Type 1 collagen and is sterilized in gamma-radiation.

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Model name	Size		
	Width (mm)	Length (mm)	Thickness (mm)
GCM1020	10	20	0.3
GCM1515	15	15	
GCM1520	15	20	
GCM2030	20	30	
GCM2530	25	30	
GCM3040	30	40	

5. Indication for use

GENOSS Collagen Membrane is intended to be used during guided bone and guided tissue regeneration procedures as a biodegradable barrier membrane into bony defects surrounding teeth and on alveolar ridges.

- Periodontal/infrabony defects
- Ridge augmentation
- Extraction sites (implant preparation/placement)
- Guided bone regeneration (GBR) procedures
- Sinus lifts

6. Technological Characteristics

GENOSS Collagen membrane has the similar technological characteristics as the predicate device; main material, indication for use and design. Technological characteristics of GENOSS Collagen membrane, RCM6 membrane, FORTAGEN ORAL membrane, OSSIX -PLUS are as following

GENOSS Collagen Membrane	
Indication for use	GENOSS Collagen Membrane is intended to be used during guided bone and guided tissue regeneration procedures as a biodegradable barrier membrane into bony defects surrounding teeth and on alveolar ridges. - Periodontal/infrabony defects - Ridge augmentation - Extraction sites (implant preparation/placement) - Guided bone regeneration (GBR) procedures - Sinus lifts
Material	Type I bovine collagen

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Crosslinking	Carbodiimide (EDC)
Sterilization	Gamma Irradiation

RCM6 membrane	
Indication for use	RESORBABLE COLLAGEN MEMBRANE is intended for use in oral surgical procedures as a resorbable material for placement to aid in wound healing in the areas of dental implants, bone defects, periodontal defects and ridge augmentation. - Ridge Augmentation - Bone Regeneration around Implants - Sinus Window - Extraction Sites - Periodontal Defects
Material	Type I bovine collagen
Crosslinking	Formaldehyde (FA)
Sterilization	Gamma Irradiation

FORTAGEN ORAL MEMBRANE	
Indication for use	FortaGen Oral Membrane is intended to be used during guided bone and guided tissue regeneration procedures as a biodegradable barrier membrane for: - Ridge augmentation for later implant insertions; - Simultaneous ridge augmentation and implant insertions; - Ridge augmentation around implants inserted in delayed extraction sites; - Ridge augmentation around implants inserted in immediate extraction sites; - Alveolar ridge preservation consequent to tooth (teeth) extraction(s); - Over the window in lateral window sinus elevation procedures; - In implants with vertical bone loss due to infection, - In implants with vertical bone loss due to infection, only in cases where satisfactory debridement and implant surf8ace disinfection can be achieved; - In intra bony defects around teeth - For treatment of recession defects, together with coronally positioned flap; - In furcation defects in multi-rooted teeth.

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Material	Type I porcine collagen
Crosslinking	Carbodiimide (EDC)
Sterilization	Gamma Irradiation

OSSIX -PLUS	
Indication for use	OssixHt-PLUS biodegradable collagen membrane is intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier for: - Ridge augmentation for later implant insertions. - Simultaneous ridge augmentation and implant insertions. - Ridge augmentation around implants inserted in delayed extraction sites. - Ridge augmentation around implants inserted in immediate extraction sites. - Alveolar ridge preservation consequent to tooth (teeth) extraction(s). - Over the window in lateral window sinus elevation procedures. - In implants with vertical bone loss due to infection, only in cases where satisfactory debridment and implant surface disinfection can be achieved. - In intra bony defects around teeth. - For treatment of recession defects, together with coronally positioned flap - In furcation defects in multi rooted teeth.
Material	porcine collagen
Crosslinking	GLYMATRIXS (ribose)
Sterilization	Gamma

7. Performance Data

Biocompatibility testing on the proposed GENOSS Collagen Membrane has been completed. Requirements for biological evaluation of the proposed device were based on the Blue Book Memorandum G95-1 issued on May 1, 1995, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices, Part I: Evaluation and Testing." The biocompatibility test results show that the materials used in the design and manufacture of the components of the proposed device are non-toxic and non-sensitizing to biological tissues consistent with its intended use. The following biocompatibility tests were completed:

-ISO Cytotoxicity
-ISO Systemic toxicity
-ISO Pyrogencity
-ISO Sensitization

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-ISO Intracutaneous reactivity
-ISO Implantation
-ISO Genotoxicity(Ames)
-ISO Genotoxicity(Sister chromatid)
-ISO Genotoxicity(Micro-nucleus)
-ISO Haemocompatibility
-ISO Elution assay

The proposed GENOSS Collagen Membrane was evaluated using the following in-vitro performance bench testing to confirm the performance characteristics:

-Shrink temperature (DSC)
-Tensile strength
-Decomposition time
-Swelling

Also, raw material was evaluated in accordance with ASTM F2212-08 to confirm the safety of collagen raw material:

-Virus inactivation
-Endotoxin
-Amino acid analysis
-SDS-PAGE

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the GENOSS Collagen Membrane met the established specifications necessary for consistent performance according to its intended use.

8. Conclusion

Based on the information provided in this premarket notification GENOSS Co., Ltd. concludes that GENOSS Collagen Membrane is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Genoss Company, Limited
C/O Dr. Eunkyung Son
Dentium USA
11075 Knott Avenue, Suite A
Cypress, California 90630

MAY - 4 2011

Re: K102307
Trade/Device Name: GENOSS Collagen Membrane
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPL
Dated: April 26, 2011
Received: May 2, 2011

Dear Dr. Son:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

GENOSS

Indication for use

510(k) Number: K102307

Device Name: GENOSS Collagen Membrane

Indication for use:

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- Guided bone regeneration (GBR) procedures
- Sinus lifts

Prescription Use ___√___ **AND/OR** **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices